



APR 10 2012

K113548  
175 Titus Ave, Suite 300  
Warrington, PA 18976  
Toll Free: 866-400-0035  
Phone: 267-483-8081  
Fax: 267-483-8086

## 510(k) Summary

<b>510 (k) Submitter/Owner</b>	CurveBeam, LLC 175 Titus Ave, Suite 300 Warrington, PA 18976 Phone: 267-483-8081 Fax: 267-483-8086
<b>Contact Person</b>	David W. Cowan Vice President of Operations 267-483-8087 Email: dave.cowan@curvebeam.com
<b>Date Prepared</b>	November 30, 2011
<b>Trade Name</b>	PedCAT
<b>Common Name</b>	Computed tomography x-ray system
<b>Classification Name</b>	Computed tomography x-ray system

### Predicate Devices:

Company	Device name	Product Code	510(k)
Imaging Sciences	DVT Scanner	JAK	K051980

### **Indications for Use:**

The PedCAT is intended to be used for 3-D imaging of the foot & ankle region, to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures. This modality is anticipated to be applicable to pediatric\* cases as well as adults\*, when appropriate diagnosis of a given foot condition is considered necessary.

\* Patient parameters: 50 lbs to 400 lbs  
Groin area at least 22" above the floor

### **Device Description:**

The PedCAT is a dedicated X-Ray imaging device that acquires a 360 degree rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The PedCAT can measure distances and thickness on two dimensional images. Images produced by the PedCAT can be printed or exported on magnetic and optical media. The PedCAT gantry is comprised of an X-ray source, image detector, and motorized gantry. The gantry facilitates the acquisition of a full X-ray sequence by the software. The software receives the two dimensional images acquired by the detector, transforms them into three dimensional images and displays them on the workstation monitor for viewing

### **Substantial Equivalence Summary:**

The intended use of the PedCAT Computed Tomography x-ray system and the predicate device is substantially similar, with certain inconsequential differences described henceforth. The PedCAT Computed Tomography x-ray system has the same technological characteristics as the predicate device in terms of the deployed Cone Beam CT technology for 3-D imaging of anatomical structures of **similar tissue density** ranges. Although the intended use differs in the target anatomy, the intended diagnostic data (osseous tissue details) and applicable tissue densities are very similar. The PedCAT also differs in its mechanical layout and the patient support structure, since it is intended for 3-D imaging of Foot & Ankle in a weight-bearing as well as non-weight bearing position.

The patient support structure is a circular rigid platform, where the patient stands, or places one or both feet if he/she sits on the adjacent seat. In the predicate device, the patient sits on a chair, while the targeted anatomy (maxillofacial region) is placed within a head support system consisting of a chin support and a headrest.

The rotating gantry in the PedCAT, on which the x-ray source and the detector panel are mounted, is enclosed in a low-density doughnut shaped plastic cover, permitting the patient's feet to be in the "doughnut-hole" opening. The predicate device has no such cover.

The above mechanical differences have no impact on how the projection data is captured and reconstructed, as compared to any CBCT device, including the predicate device. To establish this, test scans were performed on an ACR phantom, water equivalent material phantom, and an anatomic foot phantom (foot skeleton enclosed in soft tissue equivalent material). The characteristics of the resultant volume on the ACR phantom and the water equivalent phantom were authentic and accurate representations of the imaged object, within the expected tolerance for a CBCT device, and very similar to the predicate device. The specific parameters evaluated included spatial resolution (visible line pairs), uniformity of Hounsfield Units (HU's) in water equivalent material, and HU values of various density materials in the ACR phantom. The foot phantom scan showed osseous details and joint spaces very similar to the predicate device, albeit on a different anatomy but on similar tissue densities.

Further testing was performed on the clinical side. A large collection of patients have been scanned at 2 clinical sites under IRB framework, and the results have been found to be substantially similar to the predicate device, in terms of osseous details and joint spaces.

The position of the rectangular x-ray beam with respect to the target anatomy is very similar to the predicate device. In both cases, the beam is centered slightly below the center of the Field of View.

Another difference in details of a specific image acquisition mode in the PedCAT is that it performs 2 scan orbits to extend the diameter of the Field of View, with the x-ray beam and the detector offset to the left and right halves of the extended Field of View respectively. This is equivalent to having a "wider detector", but the projection geometry and other characteristics of the image acquisition process remain unchanged. The equivalence was established via test scans described above, both clinical and non-clinical (bench), which exhibited virtually identical results as compared to other scan modes. The scatter radiation was measured in

a comprehensive manner in this mode (2 scan orbits) as well, and the values were found to be in a very low range and comparable to the predicate device, although slightly higher than single-orbit scans in the PedCAT.

In the software domain, although there are expected user interface differences with the predicate device, as well as differences in certain implementation details, the frame capture tools are identical (provided by Varian, the supplier of the detector panel) and both use FDK back-projection algorithm for CBCT reconstruction.

The above tests and analysis establishes that despite certain implementation differences, the PedCAT is substantially equivalent to the predicate device.

### **Safety and Effectiveness Information:**

The PedCAT Computed tomography x-ray system is a Class II medical device and a Class 1M laser product.

The PedCAT Computed tomography x-ray system complies with applicable FDA and international standards pertaining to electrical, mechanical, software, EMC, and radiation safety of medical and / or laser devices.

### **Conclusion:**

CurveBeam, LLC has demonstrated through its comparison of characteristics with the predicate device and comparison of performance testing with the predicate device that the PedCAT Computed tomography x-ray system is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Mr. David W. Cowan  
Vice President of Operations  
CurveBeam, LLC  
175 Titus Avenue, Suite 300  
WARRINGTON PA 18976

APR 10 2012

Re: K113548

Trade/Device Name: PedCAT Computed tomography x-ray system  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK and OAS  
Dated: March 6, 2012  
Received: March 7, 2012

Dear Mr. Cowan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

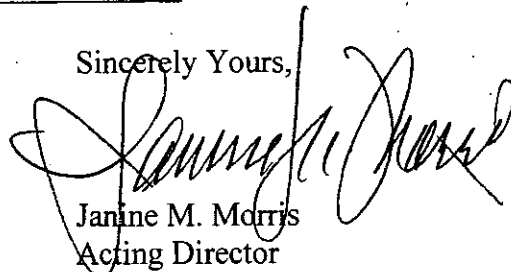
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510 (k) Number (if known) \_\_\_\_\_

Device Name: **PedCAT Computed tomography x-ray system**

### Indications for Use:

The PedCAT is intended to be used for 3-D imaging of the foot & ankle region, to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures. This modality is anticipated to be applicable to pediatric\* cases as well as adults\*, when appropriate diagnosis of a given foot condition is considered necessary.

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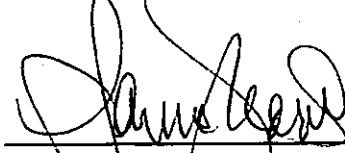
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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